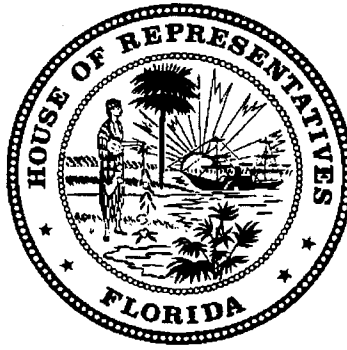




Health Care General Committee

**Monday, April 10, 2006
8:45 AM – 9:45 AM
306 HOB**

COMMITTEE MEETING PACKET



AGENDA

Health Care General Committee

April 10, 2006

8:45 a.m. – 9:45 a.m.

306 HOB

- I. Call to order/Roll Call
- II. Opening Remarks
- III. Consideration of the following bills:
 - **HB 491** - - Immunizations by Goldstein
 - **HB 855** - - Dental Laboratories by Jordan
 - **HB 1013 CS** - - Lyme Disease by Homan
- IV. Workshop on the following:
 - **HB 1073** - - Reproductive Health Services by Roberson
- V. Closing Remarks and Adjournment

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 491 Immunizations

SPONSOR(S): Goldstein and others

TIED BILLS: **IDEN./SIM. BILLS:** SB 82

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) <u>Health Care General Committee</u>		Halperin <i>PH</i>	Brown-Barrios <i>B³</i>
2) <u>Health Care Regulation Committee</u>			
3) <u>Health Care Appropriations Committee</u>			
4) <u>Health & Families Council</u>			
5) _____			

SUMMARY ANALYSIS

HB 491 prohibits, on and after July 1, 2007, the use of vaccines that contain more than specified amounts of mercury in immunizing knowingly pregnant women or children younger than 3 years of age.

The bill provides two exceptions in which knowingly pregnant women or children younger than 3 years of age may receive vaccines containing more mercury than the maximum level established in the bill. These exceptions include

- (1) declared public health emergencies, and
- (2) situations where a health care practitioner suggests that the benefits of a patient receiving a vaccine containing more mercury than the maximum established level outweigh the risks of mercury exposure, and the patient consents to receiving such a vaccine.

If enacted, the bill takes effect on the date it becomes law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide Limited Government: The bill creates additional statutory requirements and regulations for certain health care practitioners.

B. EFFECT OF PROPOSED CHANGES:

The bill prohibits, on or after July 1, 2007, the use of vaccines that contain more than specified amounts of mercury in immunizing knowingly pregnant women or children younger than 3 years of age. For influenza vaccines, the bill prohibits more than 1 microgram of mercury per 0.5-milliliter dose in vaccines administered to the target population. For all other vaccines, the bill prohibits more than 0.5 micrograms of mercury per 0.5 milliliter dose in vaccines administered to the target population.

The bill provides two exceptions in which knowingly pregnant women or children younger than 3 years of age may receive vaccines containing more mercury than the maximum level established in the bill. These exceptions are:

- (1) If the Secretary of Health declares a public health emergency and finds that an epidemic or shortage of supply of a vaccine will prevent knowingly pregnant women or children younger than 3 years of age from receiving the needed vaccine, the State Health Officer may authorize the administration of vaccine that contains more mercury than the maximum level established in the bill.¹
- (2) If according to the judgment of a licensed health care practitioner suggests, based on accepted medical standards, the benefits of the patient receiving the vaccine to prevent a vaccine-preventable disease outweigh the risks of mercury exposure. Before administering the vaccine, the practitioner must provide the patient or legal guardian with information concerning the risks and benefits of the vaccination.

This bill will not change:²

- The Department of Health's (DOH) vaccine requirements;
- The administration of required vaccines to children or pregnant women;
- Standard DOH procedure in declaring or during a public health emergency; and
- The federally required use of Vaccine Information Statements that are given to patients whenever certain vaccinations are given.

¹ Section 381.00315, F.S., provides processes for the declaring of public health emergencies.

² From the Department of Health Bill Analysis, Economic Statement, and Fiscal Note on HB 491, 12/ 22/2005.

Current Efforts to Reduce Mercury Exposure in Pharmaceuticals and Vaccines

The Food and Drug Administration (FDA) is encouraging the reduction or removal of mercury from all existing vaccines, and is working with drug manufacturers and other public health agencies to accomplish this elimination.³ Manufacturers are working to increase the supply of mercury-reduced and mercury-free vaccines used to immunize children and pregnant women against the influenza virus. To date, mercury-based preservatives have been removed or reduced to trace amounts in nearly all pharmaceuticals and pediatric vaccines; though it remains in a few required childhood shots. According to the FDA, much progress has been made in removing or reducing mercury in vaccines. Merck, Glaxo SmithKline, and Aventis Pasteur have all been licensed to develop various mercury-free vaccines. Currently, all routinely recommended vaccines for U.S. infants are available only as mercury-free, or contain only trace amounts, with the exception of the inactivated influenza vaccine. Inactivated influenza vaccines for pediatric use are available in preservative-free formulations, but are in more limited supply.⁴

Legislation to ban thimerosal from childhood vaccines has passed in seven states: New York, Tennessee, Iowa, Delaware, Illinois, Missouri, and California. Legislation in Congress (HR 881) has been introduced by Rep. Dave Weldon, M.D. (R-Florida) and Carolyn Maloney (D-NY).⁵

Florida Immunization Requirements

Section 1003.22, F.S., authorizes the Department of Health, after consultation with the Department of Education, to adopt administrative rules, that conform to recognized standards of medical practice, governing the immunization of children against, the testing for and the control of preventable communicable diseases. The department must supervise and enforce requirements, and must provide required vaccines at no cost from county health departments. Section 402.305, F.S., requires child care facilities to comply with immunization rules as a condition for licensing. Section 414.13, F.S., requires each applicant for cash assistance programs who has a preschool child to begin and complete appropriate childhood immunizations for the child as a condition of eligibility. Florida law requires immunizations for poliomyelitis, diphtheria, rubella, rubella, pertussis, mumps, tetanus, and other communicable diseases as determined by the rules of the Department of Health.⁶ The recommended childhood immunization schedule in Florida includes⁷:

Vaccine	Doses	Age(s) at Administration
Diphtheria, tetanus, and pertussis vaccine (DTaP)	5	2, 4, 6, and 12-18 months; and 4-5 years.
Polio	4	2, 4, 6-18 months; and 4-5 years.
Measles, mumps and rubella vaccine (MMR)	2	12-15 months; and at 4-5 years.
Hepatitis	3	By 12 months
Pneumococcal conjugate (Prevnar)	4	2, 4, 6 and 12 months
Haemophilus influenzae type b (Hib)	3 or 4	By 18 months.
Varicella (chickenpox)	1	Any time after 12 months.

³ Thimerosal as a vaccine preservative. *Weekly Epidemiology Record*. 2000; 75:12-16.

⁴ <http://www.fda.gov/cber/vaccine/intro>

⁵ HR 881

⁶ See Rule 64D-3.011, Florida Administrative Code.

⁷ Florida Department of Health, Immunization Schedule Information.

http://doh.state.fl.us/Disease_ctrl/immune/qi_clinical/clinical.html

A few of these immunizations still contain mercury-based preservatives. According to the Florida's Department of Health (DOH), vaccines which contain mercury that are administered to children and pregnant women include: Diphtheria-Tetanus (DT), Tetanus-Diphtheria (Td), Influenza, and Meningococcal vaccine. Completion of this series is required for school and child care center attendance in Florida. The inactivated influenza vaccine also contains mercury, and is recommended for children and pregnant women. In addition, adolescents are required to receive a Td booster vaccine prior to entering middle school, and these shots contain trace amounts of mercury, at levels considered safe by the CDC.

Mercury-Free Vaccines Available in Florida

DOH currently provides vaccine products with less than 0.5 mcg of mercury for children less than three years of age who receive shots at public health clinics. A Td product with less than 0.5 mcg of mercury is currently licensed for adults, including pregnant women. The Advisory Committee on Immunization Practices (ACIP) recommends vaccinating children and pregnant women against influenza disease. Currently there are both formulations of influenza vaccine that contain less mercury as a preservative as well as a preservative-free formulation. Mercury-free adult influenza vaccines are not always available in sufficient quantity for pregnant women.

Controversy Regarding Preservatives in vaccines

Regulations adopted by the United States Food and Drug Administration (FDA) require the addition of a preservative to multi-dose vials of vaccines.⁸ One common preservative is thimerosal⁹, a compound that is 50 percent mercury by weight. Thimerosal is used to prevent cross-contamination and the growth of harmful microbes.¹⁰ Specifically, mercury has been suggested to cause or contribute to the onset of neurodevelopmental disorders such as autism or speech and language delay. Autism is a severe and pervasive neurodevelopmental disorder characterized by a number of physical, language, and behavioral impairments.

Evidence suggesting mercury causes health and developmental problems

The proponents of removing mercury from vaccines point to the rise in the rate of autism and other neurodevelopmental problems. Other-environmental exposures to mercury (such as from dental amalgams, fish consumption, and other environmental means), are established as a risk to neural development.¹¹ Although the type of mercury in vaccines is ethylmercury, a cousin to the environmental form of mercury (methylmercury) research comparing the blood and brain levels of mercury in monkeys exposed to either methylmercury and ethylmercury demonstrate that thimerosal brings mercury into the brain; leaves higher levels of inorganic mercury in the brain than methylmercury; and that this inorganic mercury stays in the brain for years.¹² Research has further demonstrated that children with certain physiologies are impaired in their ability to detoxify mercury; that these conditions are common in children with autism; that concentrations of mercury in vaccines are neurologically harmful; and that boys are more 4 times more likely to have both this physiology and to have autism.¹³

⁸ See 21 CFR 610.15(a)

⁹ Thimerosal™ is a registered trademark of Eli Lilly

¹⁰ Thimerosal is not the only mercury-based compound that may be used as a preservative; therefore this analysis will refer interchangeably to "mercury" and "thimerosal"

¹¹ Clarkson, T.W. et al. "The toxicology of mercury – current exposures and clinical manifestations." *New England Journal of Medicine* 349:18. October 30, 2003.

¹² TM Burbacher, Shen DD, Liberato N, Grant KS, Cernichiari E, and Clarkson T. 2005. Comparison of blood and brain mercury levels in infant monkeys exposed to methylmercury or vaccines containing thimerosal. *Environ Health Perspect*: doi: 10. 1289/ehp.7712. (Online 21 April 2005)

¹³ Molecular Aspects of Thimerosal-induced Autism. Congressional Testimony by Richard C. Deth, Professor of Pharmacology, Northeastern University. See also Waly, M, Olteanu H, Banerjee R, et al. Activation of methionine

The incidence of autism has risen by about forty-fold in the past twenty years and now affects approximately one in every 166 births in the United States. According to the US Department of Education, autism is growing at a consistent rate of ten to 17 percent per year—meaning that about 4 million Americans will be living with autism in the next decade.¹⁴ National health agencies concur that autism is epidemic, and that increased rates represent true cases and not merely better reporting or diagnostics. A number of new mercury-containing immunizations were added to the battery of required vaccinations in the late 1980s. Proponents of the link between mercury and autism cite this fact and argue that this drastic increase in the cumulative amount of thimerosal exposure is responsible for causing the rise in the prevalence of autism.

In 1982, the FDA convened an expert panel reviewing mercury in over-the-counter products. It reported that thimerosal was “toxic, caused cell damage, was not effective in killing bacteria or halting their growth” and is not recognized as being “safe or effective.”¹⁵ In 1997, Congress passed the Food and Drug Administration Modernization Act that required the study of mercury content in FDA-approved products. The review revealed previously unrecognized high levels of mercury in the childhood vaccination schedule, in excess of the Environmental Protection Agency’s (EPA) limit for methylmercury.^{16,17}

These agency findings lead to a recommendation made in July 1999 by the Public Health Service (PHS) agencies and the American Academy of Pediatrics (AAP) that thimerosal be taken out of vaccines as a precautionary measure. The IOM’s Safety Review Committee concluded that the link between mercury and autism is “biologically plausible” and recommended that infants, children and pregnant women should not be exposed to thimerosal-containing vaccines.¹⁸

Evidence suggesting that mercury in vaccines does not causes health problems

The Institute of Medicine’s (IOM) Immunization Safety Review Committee concluded that evidence is inadequate to either accept or reject a causal relationship between thimerosal exposure from childhood vaccines and the onset of neurodevelopmental disorders, but that the link is “biologically plausible.” A later IOM committee concluded that the scientific evidence favors a rejection of a causal relationship between vaccines containing thimerosal and autism. The report also indicates that efforts to remove thimerosal from vaccines are a prudent course of action.¹⁹ The CDC recently conducted a study to see whether there are associations between vaccines containing thimerosal as a preservative and a wide range of neurodevelopmental disorders. Results found no consistent significant associations. Studies to examine these issues are ongoing.²⁰

Laboratory studies have tested the effect of mercury in vaccines on the concentrations of mercury in the blood. Although results between studies vary, mercury appeared to be eliminated from the blood rapidly via the stools after administration of vaccines.²¹ A recent study conducted by the National

synthase by insulin-like growth-factor-1 and dopamine: a target for neurodevelopmental toxins and thimerosal. *Molecular Psychiatry*. 2004; 9:358-70.

¹⁴ U.S. Department of Education's "Twenty-First Annual Report to Congress on the Implementation of the Individuals with Disabilities Education Act" (1999).

¹⁵ 1982 Vol. 47, No. 2 Federal Register

¹⁶ The FDA determined that in the absence of a specific standard for ethylmercury, standards for methylmercury should be used. According to the Congressional Record (reference below) ethylmercury should be considered equipotent to methylmercury as a developmental neurotoxin.

¹⁷ May 21, 2003. Congressional Record, Mercury in Medicine Report.

¹⁸ Immunization Safety Review: Thimerosal-Containing Vaccines and Neurodevelopmental Disorders (2001), Institute of Medicine. See also "Thimerosal in Vaccines" at <http://www.fda.gov/cber/vaccine/thimerosal.htm>.

¹⁹ Immunization Safety Review: Vaccines and Autism (2004). Board on Health Promotion and Disease Prevention (HPDP), Institute of Medicine (IOM). Available at <http://fermat.nap.edu/books/030909237X/html/>.

²⁰ <http://www.cdc.gov/nip/vacsafe/concerns/thimerosal/thimerosal-vacs-facts.htm>

²¹ Pichichero, M. et al. 2002. "Mercury concentrations and metabolism in infants receiving vaccines containing thimerosal: a descriptive study." *The Lancet*. Vol 360, November 30, 2002.

Institute of Allergy and Infectious Diseases (NIAID) concluded that mercury levels in the blood of babies that received vaccines with thimerosal remained well below levels considered acceptable by the EPA. Furthermore, ethylmercury thimerosal) seems to be removed from the body quickly through the gastrointestinal tract (stools).²²

A study in Denmark revealed no decrease in the prevalence of autism after thimerosal-containing vaccines were discontinued in 1992, and concludes that thimerosal plays no role in the etiology of autism.²³

In 2004, the IOM's Immunization Safety Review Committee issued its final report, examining the hypothesis that vaccines, specifically the MMR vaccines and Thimerosal containing vaccines, are causally associated with autism. In this report, the committee incorporated new epidemiological evidence from the U.S., Denmark, Sweden, and the United Kingdom, and studies of biologic mechanisms related to vaccines and autism since its report in 2001. The committee concluded that this body of evidence favors rejection of a causal relationship between thimerosal-containing vaccines and autism, and that hypotheses generated to date concerning a biological mechanism for such causality are theoretical only.²⁴

Further, the committee stated that the benefits of vaccination are proven, that the hypothesis of susceptible populations is presently speculative, and that widespread rejection of vaccines would lead to increases in incidences of serious infectious diseases like measles, whooping cough and Hib bacterial meningitis.

Research on public perception and public trust in the vaccine program

Public perception of the safety of childhood vaccines has a direct impact on immunization rates.²⁵ Thus, there are two separate problems: (1) The possible risk of thimerosal itself, and (2) The public trust in the safety of vaccines.

Some people fear that discussing the risks of mercury could cause alarm in parents and lessen their compliance with vaccine requirements, which in turn poses a threat to public health. Others suggest that leaving thimerosal in vaccines could result in the same loss of public trust. Research surveys suggest that public trust is increased when people perceive the government to be taking action to reduce risks by removing mercury from vaccines, even when those risks are not absolute.

C. SECTION DIRECTORY:

Section 1. Prohibits vaccinating a woman who is knowingly pregnant or a child who is younger than 3 years age with a vaccine that contains more than specified amounts of mercury; and provides exemptions from this requirement.

Section 2. Provides an effective date of becoming law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

²² <http://www.cdc.gov/nip/vacsafe/concerns/thimerosal/thimerosal-vacs-facts.htm>

²³ Madsen, KM, Lauritsen, MB, et al. 2003. Thimerosal and the Occurrence of Autism: Negative Ecological Evidence from Danish Population-Based Data. *Pediatrics*. 112(3): 604-606.

²⁴ See also Madsen, KM, Lauritsen, MB, et al. 2003. Thimerosal and the Occurrence of Autism: Negative Ecological Evidence from Danish Population-Based Data. *Pediatrics*. 112(3): 604-606.

²⁵ Biroscak, BJ, Fiore AE, Fasano N, et al. 2003. Impact of the thimerosal controversy on hepatitis B vaccine coverage of infants born to women of unknown hepatitis B surface antigen status in Michigan. *Pediatrics*. 107:1147-1154.

None

2. Expenditures:

The Department of Health reports that it currently orders preservative-free influenza vaccine for children aged 6 to 35 months, therefore there is no fiscal impact associated with supplying vaccine to this age group. The department noted that it could not estimate the number of pregnant women who need to be vaccinated against influenza and therefore could not accurately estimate any additional costs associated with the use of only preservative-free influenza vaccine or influenza vaccine that contains no more than 1 microgram per 0.5-milliliter dose.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Infants, children, and pregnant women may have some health benefits from a reduced exposure to mercury under the bill. There may be some increased cost associated with the purchase of preservative-free formulations, where available.

D. FISCAL COMMENTS:

There are no tax/fee issues.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill will have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

2. Other:

B. RULE-MAKING AUTHORITY:

No additional rule-making authority is required as a result of this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

HB 491

2006

A bill to be entitled

An act relating to immunizations; prohibiting vaccinating a woman who is knowingly pregnant or a child who is younger than a specified age with a vaccine that contains any mercury or injecting such a woman or child with a product that contains more than a specified amount of mercury; prohibiting vaccinating a woman who is knowingly pregnant or a child under a specified age with an influenza vaccine that contains more than a specified amount of mercury; providing the effective date of such prohibitions; providing for the State Health Officer to authorize the use of vaccines that contain a greater amount of mercury than is otherwise allowed if the Secretary of Health declares a public health emergency and makes certain findings; providing exceptions to the prohibition following disclosure regarding certain risks and benefits; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Vaccinations and injections containing mercury prohibited for pregnant women and young children.--

(1) Except for an influenza vaccine described in subsection (2), on and after July 1, 2007, a woman who is knowingly pregnant or a child who is younger than 3 years of age may not be vaccinated with a vaccine that contains any mercury or injected with a product that contains more than 0.5 micrograms of mercury per 0.5-milliliter dose.

29 (2) On and after July 1, 2007, a woman who is knowingly
30 pregnant or a child who is younger than 3 years of age may not
31 be vaccinated with an influenza vaccine that contains more than
32 1 microgram of mercury per 0.5-milliliter dose.

33 (3) If the Secretary of Health declares a public health
34 emergency under s. 381.00315, Florida Statutes, and finds that
35 an epidemic or shortage of supply of a vaccine will prevent
36 knowingly pregnant women and children younger than 3 years of
37 age from receiving the needed vaccine, the State Health Officer
38 may authorize the administration of a vaccine containing more
39 mercury than the maximum level established in subsection (1), or
40 subsection (2) in the case of influenza vaccine, to knowingly
41 pregnant women or children younger than 3 years of age.

42 (4) A licensed health care practitioner may only
43 administer a vaccine containing more mercury than the maximum
44 level established in subsection (1), or subsection (2) in the
45 case of influenza vaccine, to a knowingly pregnant woman or a
46 child younger than 3 years of age if, according to the
47 practitioner's medical judgment under accepted medical
48 standards, the benefits of the patient receiving the vaccine to
49 prevent a vaccine-preventable disease outweigh the risks of
50 mercury exposure. Before administering the vaccine, the
51 practitioner must provide to the patient or the patient's legal
52 guardian information concerning the risks and benefits of the
53 vaccination.

54 Section 2. This act shall take effect upon becoming a law.

Overview of Strike-All Amendment for HB 491

This strike-amendment to HB 491 calls for an autism epidemiology study and review of the literature to be conducted. Findings from the study will be reported to the Governor, the President of the Senate, and the Speaker the House of Representatives by October 1, 2007.

The study shall be conducted by DOH in partnership with:

- Regional autism centers (pursuant to s. 1004.55)
- Agency for Persons with Disabilities (APD)
- Department of Education (DOE)
- Developmental Disabilities Council
- The department may consult with state or private FL university medical schools and pharmacy schools in conducting the study.

The goal of the study is to gain a better understanding of the:

- prevalence in Florida of autism;
- unique demographic characteristics of the autistic population;
- effect family history, the effect of routinely recommended childhood vaccines;
- effect of other possible environmental exposure to thimerosal and ethyl mercury; and
- effect of other toxic chemicals and other environmental factors that may be presumed to impact or may be associated with the emergence of autism.

The amended bill also calls for the development and display of notices in practitioner offices regarding the use of mercury/thimerosal in vaccines.

- The DOH shall prepare two notices for health care practitioners that administer routinely recommended childhood vaccines to children under the age of three.
- The notices will be written in simple language.
- The notices will be displayed in a conspicuous location in the office or location where the vaccination takes place.

Notice 1: For practitioners using routinely recommended childhood vaccines that contain mercury, the notice shall contain at a minimum:

- A statement regarding the use of mercury-containing vaccines by the practitioner.
- An official statement or position from federal agencies regarding mercury in vaccines.
- The website address of DOH pertaining to routinely childhood immunization.
- The website address of the CDC and NIH pertaining to the latest scientific knowledge regarding mercury in vaccines.

Notice 2: For practitioners not using a vaccine containing mercury, the notice shall state a minimum:

- A statement that the practitioner uses vaccines that are free of mercury.
- The website address of DOH pertaining to childhood vaccines immunization.
- The website address of the CDC and NIH pertaining to the latest scientific knowledge regarding mercury in vaccines.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 01 (for drafter's use only)

Bill No. **HB 491**

COUNCIL/COMMITTEE ACTION

ADOPTED _____ (Y/N)
ADOPTED AS AMENDED _____ (Y/N)
ADOPTED W/O OBJECTION _____ (Y/N)
FAILED TO ADOPT _____ (Y/N)
WITHDRAWN _____ (Y/N)
OTHER _____

Council/Committee hearing bill: Health Care General Committee
Representative(s) Harrell offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Autism study.--

(1) The Department of Health, in partnership with the regional autism centers pursuant to s. 1004.55, and in consultation with the Agency for Persons with Disabilities, the Department of Education, and the Developmental Disabilities Council shall conduct an autism epidemiology study and review of the literature. The goal of the study is to gain a better understanding of:

(a) the prevalence in Florida of autism;

(b) the unique demographic characteristics of the autistic population;

(c) the effect family history, the effect of routinely recommended childhood vaccines;

(d) the effect of other possible environmental exposure to thimerosal and ethyl mercury; and

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HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 01 (for drafter's use only)

(e) the effect of other toxic chemicals and other environmental factors that may be presumed to impact or may be associated with the emergence of autism.

(2) The department may consult with state or private Florida university medical schools and pharmacy schools in conducting this study.

(3) The department shall submit a report of its findings to the Governor, the President of the Senate, and the Speaker the House of Representatives by October 1, 2007.

Section 2. Department of Health - Administration of routinely recommended childhood vaccines notice--

(1) The Department of Health shall prepare two notices for any health care practitioner as defined in 456.001(4) that administer routinely recommended childhood vaccines to children under the age of three for display in the office or location where the vaccination takes place. The notices shall be written in simple language so that it is understandable by the general population.

(2) If the health care practitioner uses a vaccine containing thimerosal, the notice shall contain at minimum:

(a) A statement regarding the use of thimerosal or ethyl mercury-containing routinely recommended childhood vaccines by the health care practitioner; and

(b) An official statement or position from the federal government agencies on thimerosal and ethyl mercury in routinely recommended childhood vaccines.

(c) The website address of the Department Health pertaining to routinely recommended childhood vaccines and immunization.

(d) The website address of the Center for Disease Control, and National Institute of Health pertaining to the latest

04/07/2006 10:54 a.m.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 01 (for drafter's use only)

scientific knowledge regarding the use of thimerosal and ethyl mercury in routinely recommended childhood vaccines.

(3) If the health care practitioner does not use a vaccine containing thimerosal or ethyl mercury, the notice shall state a minimum:

(a) A statement that the health care practitioner uses routinely recommended childhood vaccines that are free of thimerosal or ethyl mercury.

(b) The website address of the Department Health pertaining to routinely recommended childhood vaccines and immunization.

(c) The website address of the Center for Disease Control, and National Institute of Health pertaining to the latest scientific knowledge regarding the use of thimerosal and ethyl mercury in routinely recommended childhood vaccines.

Section 3. Notice to the Public.--

Any health care practitioner as defined in 456.001(4) that administers routinely recommended childhood vaccine to a child under the age of three shall have in the office or location where the vaccination takes place an applicable notice pursuant to this act regarding vaccination as prepared by the department of Health pursuant to this act. The notice of vaccine effect shall be displayed in a location conspicuous to the public or as required by the department of Health.

Section 4. This act shall take effect January 1, 2007.

===== T I T L E A M E N D M E N T =====

Remove the entire title and insert:

A bill to be entitled

04/07/2006 10:54 a.m.

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h0491-HCG-0601cr-strikeall

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 01 (for drafter's use only)

82 | An act relating to routinely recommended childhood
83 | vaccines; requiring the department to prepare a notice
84 | for any health care practitioner that administers
85 | routinely recommended childhood vaccines for display in
86 | the office or location where the vaccination takes place,
87 | providing notice requirements; requiring certain health
88 | care practitioners that administers routinely recommended
89 | childhood vaccines to post a notice to the public prepared
90 | by the department of Health; providing an effective date.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS - Revised

BILL #: HB 855 Dental Laboratories
SPONSOR(S): Jordan and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 948

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) <u>Health Care General Committee</u>	<u></u>	<u>Brown-Barrios</u>	<u>Brown-Barrios</u>
2) <u>Health Care Regulation Committee</u>	<u></u>	<u></u>	<u></u>
3) <u>Health Care Appropriations Committee</u>	<u></u>	<u></u>	<u></u>
4) <u>Health & Families Council</u>	<u></u>	<u></u>	<u></u>
5) <u></u>	<u></u>	<u></u>	<u></u>

SUMMARY ANALYSIS

HB 855 requires Florida dentists to use only the services of registered dental laboratories for the purpose of constructing, altering, repairing, or duplicating any denture, partial denture, bridge splint, or orthodontic or prosthetic appliance. The bill requires dental laboratories operating or conducting business in Florida regardless of where they are located to register with the Department of Health (DOH) and comply with state law and applicable rules. The bill makes conforming changes in the procedures that must be followed to reflect this requirement. The bill requires that beginning July 1, 2009, a dental laboratory operating or conducting business in Florida employ at least one dental technician certified by the National Board for Certification in Dental Laboratory Technology.

If enacted, the bill takes effect July 1, 2006.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide Limited Government – The bill places additional requirements on Florida dentists, DOH and dental laboratories operating or conducting business in Florida.

B. EFFECT OF PROPOSED CHANGES:

Florida dentist could only use the services of registered dental laboratories for crowns, bridges, dentures, and other dental prosthetics work. Dental laboratories would need to employ at least one certified dental technician beginning July 1, 2009 and submit the documentation with its biennially registration with DOH. Dental laboratories operating or conducting business in Florida regardless of where they are located would be required to register with DOH and comply with state law and applicable rules. DOH would need to conduct periodic inspections of dental laboratories operating or conducting business in Florida including dental laboratories that might be located in other states or countries.

BACKGROUND

Use of Unlicensed Person

Current law requires licensed dentists who use the services of any unlicensed person for constructing, altering, repairing, or duplicating any denture, partial denture, bridge splint, or orthodontic or prosthetic appliance to furnish a written work order to that person in a form prescribed by rule of the Board of Dentistry. A copy of the work order must be retained in a permanent file in the dentist's office for a period of four years, and the original work order must be retained in a permanent file for a period of two years by the unlicensed person in her or his place of business. The permanent file of work orders must be open for inspection at any reasonable time by DOH or its duly constituted agent. A dentist's failure to maintain permanent records of the work orders makes the dentist liable for a license revocation or suspension.¹

Dental Laboratories

A dental laboratory is defined as:

[A]ny person, firm, or corporation who performs for a fee of any kind, gratuitously, or otherwise, directly or through an agent or employee, by any means or method, or who in any way supplies or manufactures artificial substitutes for the natural teeth, or who furnishes, supplies, constructs, or reproduces or repairs any prosthetic denture, bridge, or appliance to be worn in the human mouth or who in any way holds itself out as a dental laboratory.²

The definition of dental laboratory excludes any dental laboratory technician who constructs or repairs dental prosthetic appliances in the office of a licensed dentist for such dentist only and under her or his supervision and work order.

Every dental laboratory operating in Florida must register with DOH every two years.³ The registration fee is \$200 and there are penalties for failure to comply with the registration requirements.⁴ There are currently 1143 registered dental laboratories operating in the state. However, many out of state and out of country laboratories are currently being utilized by Florida dentists, and are not registered with

¹ s. 466.021, F.S.

² s. 466.031, F.S.

³ s. 466.032, F.S.

⁴ F.A.C. 64B27-1.002

DOH because they are not operating in Florida.⁵ DOH is required to perform periodic inspection of dental laboratories operating in the state but is not required to perform inspections for dental laboratories outside of Florida. Each dental laboratory must comply with practice requirements and a procedure delineated in rules and is subject to periodic inspections at least one time during each calendar year.⁶ Eighteen legally sufficient complaints against dental laboratories were received by DOH in fiscal year 2004/05, mainly resulting from unsanitary conditions upon inspection by staff or expired dental laboratory licenses.⁷

DOH is prohibited from requiring an examination to operate as a dental laboratory, but is required to issue a registration certificate upon completion of the registration form and compliance with any rules promulgated by DOH.⁸

The federal Food and Drug Administration (FDA) regulates materials used and the manufacturing process but not the final product of dental laboratories. These regulations apply to any finished device intended for human use that is manufactured, imported, or offered for import in any state.⁹ The 1997 Food and Drug Modernization Act, requires all foreign dental laboratories to register and list with the FDA.¹⁰

As with most market sectors, globalization is also affecting the U.S. dental laboratory market. Pressure to keep cost down is increasingly shifting dental laboratory work to offshore establishments. Foreign laboratories that cater to the U.S. market offer cost-effective pricing. Overseas laboratories charge fees that are typically one-half to two-thirds lower compared to U.S. dental laboratories. For some U.S. laboratory owners, out sourcing to overseas laboratories is an important factor in their ability to expand their laboratories or keep cost down.¹¹

Dental Laboratory Technicians - Description of Occupation¹²

Dental laboratory technicians fill prescriptions from dentists for crowns, bridges, dentures, and other dental prosthetics. Nationally, dental laboratory technicians held about 47,000 jobs in 2002. Approximately 7 out of 10 jobs were in medical equipment and supply manufacturing laboratories, which usually are small, privately owned businesses with fewer than five employees. However, some laboratories are large; a few employ more than 50 technicians. Some dental laboratory technicians work in offices of dentists.

Most dental laboratory technicians learn their craft on the job. They begin with simple tasks, such as pouring plaster into an impression, and progress to more complex procedures, such as making porcelain crowns and bridges. Becoming a fully trained technician requires an average of 3 to 4 years.

Training in dental laboratory technology is also available through community and junior colleges, vocational-technical institutes, and the U.S. Armed Forces. Formal training programs vary greatly both in length and in the level of skill they impart. In 2002, 25 programs in dental laboratory technology were approved (accredited) by the Commission on Dental Accreditation in conjunction with the American Dental Association (ADA). These programs provide classroom instruction in dental materials science, oral anatomy, fabrication procedures, ethics, and related subjects. In addition, each student is given supervised practical experience in a school or an associated dental laboratory. Accredited programs normally take 2 years to complete and lead to an associate degree. Graduates of 2-year training programs need additional hands-on experience to become fully qualified. Each dental laboratory owner

⁵ Department of Health Bill Analysis HB 855

⁶ F.A.C. 64B27-1.001

⁷ Department of Health Bill Analysis HB 855

⁸ s. 466.033, F.S.

⁹ 21 CFR 820 and 872

¹⁰ Public Law 105-115

¹¹ Offshore outsourcing: shopping in a global market, April 2005, *Lab Management Today*,

<http://www.lmtcommunications.com/articles/offshoreoutsourcing.asp>

¹² Source: U.S. Department of Labor, Bureau of Labor Statistics 2005. <http://www.bls.gov/oco/pdf/ocos238.pdf>

operates in a different way, and classroom instruction does not necessarily expose students to techniques and procedures favored by individual laboratory owners.

The National Board for Certification, an independent board established by the National Association of Dental Laboratories (NADL), offers certification in dental laboratory technology.

The overall dental health of the population has improved because of fluoridation of drinking water, which has reduced the incidence of dental cavities, and greater emphasis on preventive dental care since the early 1960s has also improve the overall dental health of the population. As a result, full dentures will be less common, as most people will need only a bridge or crown. However, during the last few years, demand has arisen from an aging public that is growing increasingly interested in cosmetic prostheses.

Job opportunities for dental laboratory technicians should be favorable, despite expected slower-than-average growth in the occupation through the year 2012. Employers have difficulty filling trainee positions, probably because entry-level salaries are relatively low and because the public is not familiar with the occupation.

The mean hourly wage in 2005 for dental laboratory technicians in Florida was \$16.50. The mean annual wage or salary was \$34,333. The number of dental laboratory technicians employed in Florida in 2004 was 4,454. It is projected that in 2012 there will be 5,114. This represents an annual average growth rate of 1.8 percent, slower than 1.9 percent growth rate for all occupations in Florida.¹³

Growth plus replacement needs for dental laboratory technicians in Florida are estimated to average about 177 openings per year. Of these estimated 177 openings per year, 46.9 percent of these openings are due to growth (new positions) and 53.1 percent of these openings are due to replacements. This compares with all occupations in Florida where 46.7 percent of annual openings are due to growth and 53.3 percent of annual openings are due to replacements. These figures do not take into account how many workers will be competing for these openings. The industry with the highest employment for dental laboratory technicians in Florida for 2004 was Medical Equipment and Supplies Manufacturing with 73.8 percent of the total employment. The next largest industry for this occupation was Undefined Self-Employed Workers, Primary Job with 13.1 percent of the total employment. The third largest was Industry Offices of Dentists with 8.4 percent of the total employment.¹⁴

Dental Laboratory Technicians Certification

The requirements for certification as a dental technician by the National Board for Certification in Dental Laboratory Technology (NBC) include either five years of experience as a dental technician or a combination of five years of experience and formal education and three examinations.¹⁵ A person with the experience and/or educational background must take three examinations to be certified. The three examinations are taken in any order within a four-year period include: a written comprehensive, a specialty practical, and a specialty written.¹⁶ The five specialties to choose from are:

- complete dentures
- partial dentures
- crown and bridge
- ceramics
- orthodontics

The fees for the three examinations:

- Comprehensive Written Exams: \$190
- Specialty Written Exams: \$190
- Practical Exam: \$455

¹³ Employ Florida Marketplace <http://www.employflorida.com/>

¹⁴ Ibid

¹⁵ Source: The National Board for Certification in Dental Laboratory Technology <http://www.nbccert.org>

¹⁶ Ibid

There is financial assistance available to meet this cost for certain qualified individuals from the NADL.¹⁷

In addition, to maintain the certified dental technician designation a person must accumulate on an annual basis 12 hours of continuing education credit during the one-year renewal cycle. Those requirements include:

- One hour of documented infectious disease control or other documented Occupational Safety & Health Administration (OSHA) compliance education.
- Six hours must be documented scientific credit, which at least three hours must be NBC-Pre approved courses.
- Five hours in any of the following: documented scientific, infection control, or professional development credits, or other non-documented credit.

There are three accredited dental laboratory technology education programs in Florida where a person may pursue a two-year program of education in dental laboratory technology. The cost to complete a dental laboratory technology program ranges from \$1,100 to \$3,700. There is financial aid and scholarships available for students enrolled in these programs.¹⁸ The accredited programs in dental laboratory technology include:

- Indian River Community College, Ft Pierce
- Lindsey Hopkins Technical Educational Center, Miami
- McFatter Vocational Technical School, Davie (Broward County)

According to the NADL the benefits of becoming a certified dental technician include:

- Demonstration of a significant mastery of knowledge needed in dental technology.
- Demonstration of a significant mastery of applied skills needed in dental technology.
- Demonstration of competency to peers and the public.
- Indication of being at the top of the dental technology profession.
- Establishing a basis for networking, professional recognition, friendships and life-long learning.¹⁹

Current law does not require that a certified dental technician be employed in a dental laboratory to operate in Florida. There are 426 certified dental laboratory technicians in this state.²⁰

C. SECTION DIRECTORY:

Section 1. Amends s. 466.021, F.S.

Section 2. Amends s. 466.032, F.S.

Section 3. Provides an effective date of July 1, 2006.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

¹⁷ The NADL Pillar Scholarship is designed to allow qualified candidates the opportunity to sit for the three examinations that comprise the Certified Dental Technician examination process. The Pillar Scholarship covers the application and testing fees for a candidate to take the written comprehensive exam, the written specialty exam and the hands-on practical examination, one time each. It also awards the candidate a certificate that can be used to purchase study materials through NADL. <http://www.nadl.org/Scholarship.shtml>

¹⁸ The Florida Dental Health Foundation in cooperation with the Florida Dental Laboratory Association and the faculty of the accredited training programs, awards scholarships to needy students enrolled in a dental laboratory technology program. Source Florida Dental Association. <http://www.floridadental.org/public/careers/labtech.html>. In addition, other types of financial support are available through the Department of Education. <http://www.firn.edu/doe/bin00065/splist.htm>

¹⁹ NADL http://www.nbccert.org/why_cdt.shtml

²⁰ Department of Health Bill Analysis HB 855

1. Revenues:

DOH could not determine the specific amount of the revenue associated with act. (See Fiscal Comments)

2. Expenditures:

DOH could not determine the specific amount of expenditures associated with this act. (See Fiscal Comments)

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None

2. Expenditures:

None

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

If certified dental technicians command higher wages, then there is a possibility the employment of certified dental technicians as required by this act may increase the operating costs of a dentist and as a result could increase the cost to the consumer.

A one person operation would have to become a certified dental technician, hire an individual that is certified, seek employment in a laboratory that employs a certified dental technician or work in the office of a licensed dentist in order to meet the July 1, 2009 deadline for certification.

There are 426 certified dental laboratory technicians in this state and 1143 registered dental laboratories operating in the state. Even if one assumed that each of 426 certified technicians work in different dental laboratories, there would be a need for a minimum of 717 additional certified dental laboratory technicians within the next three years to comply with the requirements of this bill.²¹ The need for certified technician will obviously be greater because it is unlikely that all current certified dental technicians in Florida work in different laboratories, because of the already noted favorable growth rate for the industry, and because of the predicted growth of Florida's population.²²

The private organizations that have training programs and prepare an individual to take the certification examinations and continuing education requirements could experience an increase in demand and revenue. The National Board for Certification in Dental Laboratory Technology could experience an increase in demand for examinations and increase in revenue from examination fees and other related educational materials.

D. FISCAL COMMENTS:

According to DOH, the state may realize an increase in revenue from registration by out of state and out of country dental labs which would be required to register under this new law. There would be an expense associated with the inspection of these out of state and out of country dental laboratories.²³

DOH also anticipates the potential for an increase in the number of complaints that would require investigation and prosecution but could not estimate the costs of these investigations and prosecutions.

²¹ This scenario excludes the effect of the bill on dental laboratories located outside the state of Florida but doing business in the state.

²² Florida's current population of approximately 18.5 million is expected to be 19.3 million by 2009. Source: FI Legislature Office of Economic and Demographic Research <http://edr.state.fl.us/index.html>

²³ Department of Health Bill Analysis HB 855

Some types of complaints may include 1) the dentist is not using a dental laboratory that is employing a certified dental technician; 2) the dentist is not using a registered dental laboratory; or 3) the dental laboratory does not have a certified dental technician.²⁴

There could be an increase in enrollment in public educational facilities that provide a program of education in dental laboratory technology.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or take action requiring the expenditure of funds. This bill does not reduce the percentage of state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

None

B. RULE-MAKING AUTHORITY:

Current law provides DOH rule making authority to address changes in rules to address the requirements of this act.²⁵

C. DRAFTING ISSUES OR OTHER COMMENTS:

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

²⁴ Ibid

²⁵ s. 466.038, F.S.

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1 A bill to be entitled

2 An act relating to dental laboratories; amending s.
3 466.021, F.S.; revising the services that a dentist may
4 use for constructing orthodontic or prosthetic appliances
5 to require that a dentist use the services of a registered
6 dental laboratory; amending s. 466.032, F.S.; requiring
7 that a dental laboratory employ a certified dental
8 technician by a specified date in order to register with
9 the Department of Health; providing an effective date.

10
11 Be It Enacted by the Legislature of the State of Florida:

12
13 Section 1. Section 466.021, Florida Statutes, is amended
14 to read:

15 466.021 Employment of registered dental laboratories
16 ~~unlicensed persons~~ by dentist; penalty.--Every duly licensed
17 dentist who uses the services of any registered dental
18 laboratory ~~unlicensed person~~ for the purpose of constructing,
19 altering, repairing, or duplicating any denture, partial
20 denture, bridge splint, or orthodontic or prosthetic appliance
21 shall be required to furnish the registered dental laboratory
22 ~~such unlicensed person~~ with a written work order in the ~~such~~
23 form ~~as~~ prescribed by rule of the board. This form shall be
24 dated and signed by the ~~such~~ dentist, ~~and~~ shall include the
25 patient's name or number with sufficient descriptive information
26 to clearly identify the case for each separate and individual
27 piece of work, and shall also include the Florida registration
28 number of the dental laboratory performing the work. A copy of

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29 the ~~such~~ work order shall be retained in a file in the dentist's
30 office for a period of 4 years, and the original work order
31 shall be retained in a file for a period of 4 years by the
32 registered dental laboratory ~~such unlicensed person in her or~~
33 ~~his place of business.~~ The ~~Such~~ file of work orders to be kept
34 by the ~~such~~ dentist or by the registered dental laboratory ~~such~~
35 ~~unlicensed person~~ shall be open to inspection at any reasonable
36 time by the department or its duly constituted agent. Failure of
37 the dentist to keep records of the ~~such~~ work orders shall
38 subject the dentist to suspension or revocation of her or his
39 license to practice dentistry. Failure of a registered dental
40 laboratory to have the original or electronic copy of the ~~such~~
41 ~~unlicensed person to have in her or his possession a work order~~
42 as required by this section ~~is~~ shall be admissible evidence of a
43 violation of this chapter and constitutes ~~shall constitute~~ a
44 misdemeanor of the second degree, punishable as provided in s.
45 775.082 or s. 775.083. This section does not preclude a
46 registered dental laboratory from working for another registered
47 dental laboratory if, ~~provided that~~ ~~such~~ work is performed
48 pursuant to written authorization, in a form to be prescribed by
49 rule of the board, which evidences that the originating
50 laboratory has obtained a valid work order and which sets forth
51 the work to be performed. This section does not preclude a
52 registered laboratory from providing its services to dentists
53 licensed and practicing in another state if, ~~provided that~~ ~~such~~
54 work is requested or otherwise authorized in written form that
55 ~~which~~ clearly identifies the name and address of the requesting
56 dentist and ~~which~~ sets forth the work to be performed.

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Section 2. Section 466.032, Florida Statutes, is amended to read:

466.032 Registration.--

(1) Every person, firm, or corporation operating or conducting business as a dental laboratory in this state shall register biennially with the department on forms to be provided by the department and, at the same time, pay to the department a registration fee not to exceed \$300 for which the department shall issue a registration certificate entitling the holder to operate a dental laboratory for a period of 2 years. Effective July 1, 2009, a dental laboratory shall employ at least one dental technician certified by the National Board for Certification in Dental Laboratory Technology during the period of its registration and shall submit the documentation with its registration.

(2) Upon the failure of any dental laboratory operator to comply with subsection (1), the department shall notify her or him by registered mail, within 1 month after the registration renewal date, return receipt requested, at her or his last known address, of the ~~such~~ failure and inform her or him of the provisions of subsections (3) and (4).

(3) Any dental laboratory operator who has not complied with subsection (1) within 3 months after the registration renewal date shall be required to pay a delinquency fee of \$40 in addition to the regular registration fee.

(4) The department is authorized to commence and maintain proceedings to enjoin the operator of any dental laboratory who has not complied with this section from operating or conducting

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85 business as a dental laboratory in this state until she or he
 86 has obtained a registration certificate and paid the required
 87 fees.

88 Section 3. This act shall take effect July 1, 2006.

Key Features of the Strike-All for HB 855

The 855 Strike All:

- 1) **CHANGES** terms in **Existing Law** to **New Law**
“unlicensed person” to “registered dental laboratory”
“work order” to “prescription”
- 2) **REQUIRES** Dentists to disclose to the patient the materials used in the restoration and the name and the address of the dental lab where the restoration was manufactured.
- 3) **REQUIRES** Dental Offices and dental laboratories to use an OSHA approved bag for shipping of impression, other case materials and the finished dental appliance.
- 4) **REQUIRES** Every business that registers as a dental laboratory **AFTER OCTOBER 1, 2006** to prove that either the owner of the lab or a dental technician who is employed full time by the laboratory has passed the comprehensive written exam for dental technology.
- 5) **REQUIRES** Every registered dental laboratory **AFTER OCTOBER 1, 2008** upon request for renewal with the department to provide proof that that either the owner or a dental technician who is employed full time by the laboratory has completed at least 24 hours of continuing education during the 2 year registration period.

The 855 Strike All:

- 1) **DOES NOT REQUIRE** Dental laboratories to employ a Certified Dental Technician
- 2) **DOES NOT REQUIRE** Dental offices that have an in house dental laboratory physically located within their building to comply with the continuing education or testing requirements of this bill.
- 3) **DOES NOT REQUIRE** The Department of Health to inspect out of state dental laboratories.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 01a (for drafter's use only)

Bill No. **HB 855**

COUNCIL/COMMITTEE ACTION

ADOPTED ___ (Y/N)
ADOPTED AS AMENDED ___ (Y/N)
ADOPTED W/O OBJECTION ___ (Y/N)
FAILED TO ADOPT ___ (Y/N)
WITHDRAWN ___ (Y/N)
OTHER ___

1 Council/Committee hearing bill: Health Care General Committee
2 Representative(s) Jordan offered the following:
3

4 **Amendment (with title amendment)**

5 Remove everything after the enacting clause and insert:

6 Section 1. Present subsection (5) of section 466.018,
7 Florida Statutes, is renumbered as subsection (6), and a new
8 subsection (5) is added to that section to read:

9 466.018 Dentist of record; patient records; disclosure.--

10 (5) Upon final delivery of a restorative or cosmetic case
11 to a patient, such as crowns, bridges, implants, veneers,
12 orthodontic appliances, complete or partial dentures, or other
13 prosthetic devices, the dentist shall provide to the patient a
14 list of the materials used in the case, along with the chemical
15 composition and any contraindications of the materials, and
16 shall disclose the name and address of the dental laboratory at
17 which the case was manufactured.

18 Section 2. Section 466.021, Florida Statutes, is amended
19 to read:

20 466.021 Employment of registered dental laboratories
21 ~~unlicensed persons~~ by dentist; penalty.--Every duly licensed
22 dentist who uses the services of any registered dental

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HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 01a (for drafter's use only)

23 laboratory ~~unlicensed person~~ for the purpose of constructing,
24 altering, repairing, or duplicating any denture, implant,
25 veneer, partial denture, bridge splint, or orthodontic or other
26 prosthetic appliance shall be required to furnish the registered
27 dental laboratory ~~such unlicensed person~~ with a written
28 prescription work order in a such form ~~as~~ prescribed by rule of
29 the board. This prescription form shall be dated and signed by
30 the ~~such~~ dentist, ~~and shall~~ include the license number of the
31 dentist, the patient's name or number with sufficient
32 descriptive information to clearly identify the case for each
33 separate and individual piece of work, the registration number
34 of the registered dental laboratory performing the work, a
35 specification of materials desired. Additionally, materials such
36 as dental impressions shipped or delivered to a registered
37 dental laboratory by a dental office shall be shipped in a bag
38 approved by the Occupational Safety and Health Administration. A
39 copy of the prescription ~~such work order~~ shall be retained in a
40 file in the dentist's office for a period of 4 years, and the
41 original prescription work order shall be retained in a file by
42 the registered dental laboratory for a period of 4 years ~~by such~~
43 ~~unlicensed person in her or his place of business. The~~ Such file
44 of prescriptions work orders to be kept by the ~~such~~ dentist and
45 ~~or by the registered dental laboratory such unlicensed person~~
46 shall be open to inspection at any reasonable time by the
47 department or its duly constituted agent. Failure of the dentist
48 to keep records of the prescriptions ~~such work orders~~ shall
49 subject the dentist to suspension or revocation of her or his
50 license to practice dentistry. Failure of a registered dental
51 laboratory to have the original or electronic copy of the
52 prescriptions ~~such unlicensed person to have in her or his~~
53 ~~possession a work order as required by this section~~ is shall be

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HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 01a (for drafter's use only)

54 admissible evidence of a violation of this chapter and
55 constitutes ~~shall constitute~~ a misdemeanor of the second degree,
56 punishable as provided in s. 775.082 or s. 775.083. This section
57 does not preclude a registered dental laboratory from working
58 for another registered dental laboratory ~~if, provided~~ that ~~such~~
59 work is performed pursuant to written authorization, in a form
60 to be prescribed by rule of the board, that ~~which~~ evidences that
61 the originating laboratory has obtained a valid prescription
62 ~~work order~~ and that ~~which~~ sets forth the work to be performed.
63 This section does not preclude a registered laboratory from
64 providing its services to dentists licensed and practicing in
65 another state ~~if, provided~~ that ~~such~~ work is requested or
66 otherwise authorized in written form that ~~which~~ clearly
67 identifies the name and address of the requesting dentist and
68 ~~which~~ sets forth the work to be performed.

69 Section 3. Section 466.032, Florida Statutes, is amended
70 to read:

71 466.032 Registration.--

72 (1) Every person, firm, or corporation operating or
73 conducting business as a dental laboratory in this state shall
74 register biennially with the department on forms to be provided
75 by the department and, at the same time, pay to the department a
76 registration fee not to exceed \$300 for which the department
77 shall issue a registration certificate entitling the holder to
78 operate a dental laboratory for a period of 2 years.

79 (2) Any business that registers as a new dental laboratory
80 after October 1, 2006, shall as part of establishing its
81 eligibility to register provide to the department proof that
82 either the owner of the dental laboratory or a dental technician
83 who is employed full time by the dental laboratory has, at a
84 minimum, passed the comprehensive written exam for dental

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HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 01a (for drafter's use only)

85 technology as administered by the National Board for
86 Certification in Dental Laboratory Technology. This requirement
87 does not apply to a dental laboratory that is physically located
88 within a dental practice operated by a licensed dentist as
89 defined in this chapter.

90 (3) Any dental laboratory registered on or after October
91 1, 2008, shall submit proof to the department that the owner or
92 at least one dental technician employed full time by the
93 registered dental laboratory has attended a minimum of 24 hours
94 of continuing education in dental technology during the 2-year
95 registration renewal period with at least 12 hours in scientific
96 or technical courses and at least 2 hours in Occupational Safety
97 and Health Administration compliance standards for dentistry.

98 (4) Each registered dental laboratory shall provide the
99 number of technician employees and nontechnician employees
100 employed by the laboratory both on its initial registration
101 application and subsequent registration renewals with the
102 department.

103 (5)+2 Upon the failure of any dental laboratory operator
104 to comply with subsection (1), the department shall notify her
105 or him by registered mail, within 1 month after the registration
106 renewal date, return receipt requested, at her or his last known
107 address, of the ~~such~~ failure and inform her or him of the
108 provisions of subsections (6)+3 and (7)+4.

109 (6)+3 Any dental laboratory operator who has not complied
110 with subsection (1) within 3 months after the registration
111 renewal date shall be required to pay a delinquency fee of \$40
112 in addition to the regular registration fee.

113 (7)+4 The department is authorized to commence and
114 maintain proceedings to enjoin the operator of any dental
115 laboratory who has not complied with this section from operating

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HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 01a (for drafter's use only)

116 or conducting business as a dental laboratory in this state
117 until she or he has obtained a registration certificate and paid
118 the required fees.

119 Section 4. Section 466.036, Florida Statutes, is amended
120 to read:

121 466.036 Information; periodic inspections; equipment,
122 supplies and infection control.--The department may require from
123 the applicant for a registration certificate to operate a dental
124 laboratory any information necessary to carry out the purpose of
125 this chapter, including proof that the applicant has the
126 equipment and supplies necessary to operate or conduct business
127 as determined by rule of the department, and shall require
128 periodic inspection of all dental laboratories operating in this
129 state. Such inspections shall include, but not be limited to,
130 inspection of sanitary conditions, equipment, supplies, and
131 facilities on the premises. The department shall specify dental
132 equipment and supplies that are not permitted in a registered
133 dental laboratory. Cases or materials shipped or delivered to a
134 dental office by a registered dental laboratory shall be shipped
135 in a bag approved by the Occupational Safety and Health
136 Administration. The department is not required to conduct
137 inspection of any registered dental laboratory in another state
138 or country.

139 Section 5. This act shall take effect July 1, 2006.

141 ===== T I T L E A M E N D M E N T =====

142 Remove the entire title and insert:

143 An act relating to dentistry; amending s. 466.018, F.S.;
144 requiring a dentist to provide specified information to a
145 patient relating to restorative or cosmetic cases;
146 amending s. 466.021, F.S.; providing that requirements

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HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 01a (for drafter's use only)

147 relating to certain dental work apply to registered dental
148 laboratories in lieu of "any unlicensed person"; revising
149 the procedure by which a dentist may outsource certain
150 dental work; amending s. 466.032, F.S.; revising
151 provisions relating to dental laboratory registration;
152 requiring certain dental laboratories to submit specified
153 information to the Department of Health; amending s.
154 466.036, F.S.; providing that the department shall not be
155 required to conduct inspection of certain dental
156 laboratories; providing an effective date.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 01 (for drafter's use only)

Bill No. **HB 855**

COUNCIL/COMMITTEE ACTION

ADOPTED ☐ (Y/N)
ADOPTED AS AMENDED ☐ (Y/N)
ADOPTED W/O OBJECTION ☒ (Y/N)
FAILED TO ADOPT ☐ (Y/N)
WITHDRAWN ☐ (Y/N)
OTHER _____

ADOPTED
03/22/2006

1 Council/Committee hearing bill: Health Care General Committee
2 Representative(s) Jordan offered the following:
3

4 **Amendment**

5 Remove line(s) 67 and insert:

6 July 1, 2011, a dental laboratory shall employ at least one

03/14/2006 10:49 am

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h0855-017-0601cr

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No.02 (for drafter's use only)

Bill No. **HB 855**

COUNCIL/COMMITTEE ACTION

ADOPTED _____ (Y/N)
ADOPTED AS AMENDED _____ (Y/N)
ADOPTED W/O OBJECTION ✓ (Y/N)
FAILED TO ADOPT _____ (Y/N)
WITHDRAWN _____ (Y/N)
OTHER _____

ADOPTED
03/22/2006

1 Council/Committee hearing bill: Health Care General Committee
2 Representative(s) Jordan offered the following:
3

4 **Amendment (with title amendment)**

5 Remove line(s) 71 and insert:
6 registration. This requirement does not apply to a dental
7 laboratory that is physically located within a dental practice
8 as operated by a licensed dentist as defined in this chapter.
9

10
11 ===== T I T L E A M E N D M E N T =====

12 Remove line(s) 9 and insert:
13 the Department of Health; providing an exception; providing an
14 effective date.

03/14/2006 10:49 am

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h0855-017-0602cr

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 03(for drafter's use only)

Bill No. **HB 855**

COUNCIL/COMMITTEE ACTION

ADOPTED _____ (Y/N)
ADOPTED AS AMENDED _____ (Y/N)
ADOPTED W/O OBJECTION ☒ (Y/N)
FAILED TO ADOPT _____ (Y/N)
WITHDRAWN _____ (Y/N)
OTHER _____

ADOPTED
03/22/2006

Council/Committee hearing bill: Health Care General Committee
Representative(s) Jordan offered the following:

Amendment (with title amendment)

On line(s) 87 after the period insert:

Section 3. Section 466.036, Florida Statutes is amended to
read:

466.036 Information; periodic inspections; equipment and
supplies.--The department may require from the applicant for a
registration certificate to operate a dental laboratory any
information necessary to carry out the purpose of this chapter,
including proof that the applicant has the equipment and
supplies necessary to operate as determined by rule of the
department, and shall require periodic inspection of all dental
laboratories operating in this state. Such inspections shall
include, but not be limited to, inspection of sanitary
conditions, equipment, supplies, and facilities on the premises.
The department shall specify dental equipment and supplies that
are not permitted in a registered dental laboratory. The
department shall not conduct inspection of any registered dental
laboratories located in another state or country.

03/21/2006 11:00 a.m.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 03(for drafter's use only)

22

23

===== T I T L E A M E N D M E N T =====

24

On line(s) 9 after the semicolon insert:

25

Amending s. 466.036, F.S., prohibiting the Department of Health

26

from conducting inspections of registered dental laboratories

27

located in another state or country;

03/21/2006 11:00 a.m.

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h0855-017-0603cr

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1013 CS (PCS FOR HB 1013)

Lyme Disease

SPONSOR(S): Homan

TIED BILLS:

IDEN./SIM. BILLS: SB 2022

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Insurance Committee	15 Y, 0 N, w/CS	Tinney	Cooper
2) Health Care General Committee		Ciccone <i>PC</i>	Brown-Barrios <i>B3</i>
3) Fiscal Council			
4) Commerce Council			
5) _____			

SUMMARY ANALYSIS

Lyme disease (*Lyme borreliosis*) is a bacterial infection spread to humans through tick bites. When ticks are infected with this type of bacterium, they can transmit it by biting animals and humans. Lyme disease is the most common tickborne illness in the United States, although it is also found in Canada, Europe, and Asia. Current law does not require health insurers to provide specified coverage or treatment for Lyme disease.

The bill creates the Panel on Lyme Disease to be headed by the Secretary of the Department of Health, or his or her designee. Three other agency heads also serve on the panel: the Commissioner of Insurance Regulation, the Secretary of Health Care Administration (AHCA), and the Insurance Consumer Advocate, or their respective designees.

The panel is directed by the bill to study issues relating to the diagnosis and treatment of Lyme disease and to consider the following information:

1. Appropriate medical treatments and interventions;
2. Costs associated with the treatment and interventions;
3. Implications of requiring individual and group health insurance policies, as well as managed care organizations, to cover appropriate treatments of Lyme disease; and
4. Other related information identified by panel members.

The panel is directed to seek input and information from persons diagnosed as having the disease, health care providers who treat Lyme disease, health insurers, public health officials, and other parties the panel determines have pertinent information about Lyme disease. The bill requires the panel to submit a report of its findings, including recommendations and suggested legislation, if appropriate, by February 15, 2007. The panel will deliver copies of the report to the Governor, the Senate President, the Speaker of the House of Representatives, the majority and minority leaders of both the Senate and the House, and to the substantive legislative committees having oversight of health insurance. The panel is authorized to include recommendations in its report for complying with s. 624.215, F.S., if appropriate. The bill repeals provisions creating the Panel on Lyme Disease June 30, 2007.

There is minimal fiscal impact to the agencies participating in the panel for implementing the bill. The bill takes effect upon becoming law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide Limited Government and Empower Families—The bill creates a panel to study Lyme disease, including its diagnosis and treatment. The panel is required to submit a report of its findings, including possible legislation, to legislative leaders and the Governor by February 15, 2007. It is possible the panel will recommend the Legislature consider requiring individual and group health insurers to offer specified benefits to persons diagnosed with Lyme disease.

B. EFFECT OF PROPOSED CHANGES:

Lyme Disease: General Information

Lyme disease (*Lyme borreliosis*) is a bacterial infection spread to humans through tick bites. When ticks are infected with this type of bacterium, they can transmit it by biting animals and humans. Lyme disease is the most common tickborne illness in the United States, although it is also found in Canada, Europe, and Asia.¹ It was first described in the 1970s as an outbreak of arthritis in Lyme, Connecticut, and it was formally described in the medical literature in 1976.²

In the U.S., the two types of ticks that transmit Lyme disease bacteria are the deer tick (*Ixodes scapularis*), found most often in the northeastern and upper midwestern part of the country. Western black-legged ticks (*Ixodes pacificus*) are the second source of Lyme disease; they are seen most frequently along the Pacific coast, mostly in northern California and Oregon.³

The Centers for Disease Control and Prevention (CDC), an agency of the U.S. Department of Health and Human Services, is the federal agency tasked with tracking the identification, diagnosis, and treatment of Lyme disease, as well as many other infectious diseases. According to the CDC, in 2001, the first year the agency began tracking the incidence of Lyme disease, a total of 17,029 cases were reported. By 2002, the number of reported cases had risen by 40 percent, to 23,763 reported cases. In the 2002 report, only Hawaii, Montana, and Oklahoma did not report any cases of Lyme disease to the CDC.⁴

According to the CDC, in both 2001 and 2002, 12 states reported incidences of Lyme disease higher than the national average of 6 cases per 100,000 people in 2001 and 8.2 cases per 100,000 in 2002. The 12 states include Connecticut, Delaware, Maine, Maryland, Massachusetts, Minnesota, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Wisconsin. The CDC reports that an estimated 95 percent of the cases of Lyme disease identified in 2001 and 2002 were located in these 12 states.⁵ The CDC conjectures that the increase in reported cases of the disease may be due to growing populations of deer, increased residential development of wooded areas, tick dispersal to new areas, improved disease recognition in areas where Lyme disease is prevalent, and enhanced reporting.⁶

¹ Yahoo! Health; *Topic Overview: What is Lyme Disease*; available at http://health.yahoo.com/ency/healthwise/hw77226/_hw77226-credits:_ylt=AhqXjiwnU66R2HTmCJlIIM3ogrMF; viewed April 3, 2006.

² Richard G. Bachur, MD, et al.; "Lyme Disease"; eMedicine: Instant Access to the Minds of Medicine; available at: <http://www.emedicine.com/ped/topic1331.htm>; viewed April 4, 2006.

³ *Id.*; see also: Dr. Gary P. Wormser, et al.; "Guidelines from the Infectious Diseases Society of America: Practice Guidelines for the Treatment of Lyme Disease"; *Clinical Infectious Diseases*; 2000; 31 (Suppl 1): S1-14; available at: <http://www.cdc.gov/ncidod/dvbid/lyme/IDSA2000.pdf>; viewed April 3, 2006.

⁴ "Lyme Disease: United States, 2001-2002," *Morbidity and Mortality Weekly*; May 7, 2004; 53(17); 365-369; available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5317a4.htm>; viewed April 3, 2006.

⁵ *Id.*

⁶ *Id.*

Lyme Disease: Diagnosis and Treatment

The bacterium that causes Lyme disease (*Lyme borreliosis*) is transmitted to humans through the bite of ticks infected with the bacterium. Once infected, a person generally develops symptoms of the disease within a few days or weeks. Early symptoms of the disease frequently include an expanding, circular red rash, similar in appearance to a bull's eye, referred to as *erythema migrans*, and flu-like symptoms, including body aches, fatigue, swollen lymph glands, and mild fever.⁷ In the U.S., about 80 percent of those infected develop a circular rash at the site of the bite, however, some people do not develop any symptoms during the early stages of the disease.⁸

The incubation period for Lyme disease ranges from 7-14 days, although symptoms may occur as early as within 3 days or as late as 31 days after the tick bite.⁹ If the early stage of symptoms is unnoticed, later symptoms may include swelling and pain in the joints (similar to arthritis); numbness and tingling in the hands, feet, or back; persistent fatigue; poor memory and reduced ability to concentrate; and weakness or paralysis in the muscles of the face, i.e., palsy.¹⁰

Lyme disease is most often treated with antibiotics such as doxycycline or amoxicillin. Antibiotic treatment for the early stages of Lyme disease is effective, and symptoms are generally resolved within 3 weeks of treatment. It is more effective to initiate antibiotic treatment as soon as possible after infection.¹¹ Research indicates administration of a single dose of doxycycline within 72 hours after being bitten by an infected tick, eliminates the chances of developing Lyme disease by 87 percent.¹² If Lyme disease is not diagnosed and treated shortly after exposure, it may take longer to treat the disease successfully.

Delayed Diagnosis and Treatment

Lyme disease may progress in stages from mild symptoms to serious, long-term disabilities if left untreated. Health care providers have identified three stages of the disease: 1) early localized; 2) early disseminated; and 3) late persistent.

Stage 1, an early, localized infection with Lyme disease generally manifests itself within 1 to 4 weeks of a tick bite. As noted previously, an estimated 80 percent of the people infected with Lyme disease develop an expanding circular red skin rash, *erythema migrans*, within 4 weeks after being bitten by an infected tick.¹³ In up to half of the people diagnosed with Lyme disease, the expanding circular rash is accompanied by flu-like symptoms, including fatigue or lack of energy; headache and stiff neck; fever and chills; pain in the joints and muscles; and swollen lymph nodes. As many as 25 percent of infected persons have only flu-like symptoms, with no rash or no symptoms at all.¹⁴

Stage 2 occurs within 1 to 4 months after being infected and is referred to as early disseminated infection. If an infected person is not diagnosed and treated during stage 1, the infection may spread to the skin, joints, nervous system, and heart within weeks to several months after the initial infection.¹⁵ Symptoms at this stage may include persistent fatigue; additional skin rashes throughout the body; pain, weakness, or numbness in the arms or legs; inability to control facial muscles, i.e., paralysis of facial

⁷ Yahoo! Health; *Topic Overview: What is Lyme Disease*; available at http://health.yahoo.com/ency/healthwise/hw77226/_hw77226-credits_vlt=AhqXjiwnU66R2HTmCJlIM3ogrME; viewed April 3, 2006.

⁸ Centers for Disease Control and Prevention: Lyme Disease; Disease Information; Division of Vector-Borne Infectious Diseases; available at: <http://www2.ncid.cdc.gov/travel/yb/utills/ybGet.asp?section=dis&obj=lyme.htm>; viewed April 3, 2006.

⁹ American Academy of Pediatrics; 2003; Lyme Disease (*Borrelia burgdorferi* infection); *Red Book: 2003 Report of the Committee on Infectious Diseases*; L. K. Pickering, editor; 26th ed.; pp. 407-411; Elk Grove, IL.

¹⁰ See *supra*, Note 7.

¹¹ Hwang M.I.; 2000; "Dangers of Lyme Disease," *Journal of the American Medical Association*; 283(5): 698.

¹² Nadelman, R.B.; 2001; "Prophylaxis with Single-dose Doxycycline for the Prevention of Lyme Disease after an *Ixodes scapularis* Tick Bite"; *New England Journal of Medicine*; 245(2).

¹³ See *supra*, Note 7.

¹⁴ *Id.*

¹⁵ *Id.*

nerves; recurring headaches or fainting; poor memory or a reduced ability to concentrate; conjunctivitis ("pink eye"); occasional rapid heartbeats; or, in rare cases, more serious heart problems.¹⁶

If Lyme disease is not promptly or effectively treated, damage may occur to the joints, nerves, and brain. The third stage of Lyme disease, late persistent infections, causes symptoms including swelling and pain in the joints, especially the knees; severe fatigue; numbness and tingling in the hands, feet, or back; partial facial nerve paralysis; neurologic changes, including problems with mood, memory, sleep, and sometimes with speaking; chronic Lyme arthritis, including recurrent episodes of swelling, redness, and fluid buildup in one or more joints.¹⁷ Heart, nervous system, and joint symptoms may be the first signs of Lyme disease in persons who do not develop an early rash or other symptoms of early infection.¹⁸

The prognosis for Lyme disease generally is excellent when patients are treated early with appropriate antibiotic regimens. For patients with chronic symptoms post infection, randomized controlled trials of extended antibiotic regimens have not proven to be effective.¹⁹ Patients in the third stage of Lyme disease face the most difficulty in diagnosing and treating the disease. It is generally these patients, many of whom may have suffered from the disease for years, who advocate new or experimental treatments, many of which may not be covered by health insurers or managed care organizations.

Current Florida Law Governing Health Insurance

Current Florida law specifying the coverage and benefits health insurers must include in health policies do not specify treatment or require a benefit specific to Lyme disease. This means individual and group health insurers, as well as managed care organizations, determine their respective benefits and coverage for Lyme disease through the insurance contract/policy. As a result, different health insurers may cover Lyme disease treatments at different levels, or not at all.

Although the law does not specify the types of treatment and benefits a health insurer must offer, the law provides general guidelines regarding coverage. For example, in s. 627.411, F.S., which governs insurance contracts/policies, generally, the law authorizes OIR to disapprove an insurance form if it is ambiguous or if the form contains information that deceptively affects the risk covered by the policy. Similarly, the law requires a health policy to be clear in specifying the services or treatments that are not covered by the policy.

Similar provisions in current law govern the services offered by a health maintenance organization (HMO) or other managed care policy. For example, in s. 641.19(11), the law requires a health maintenance contract to provide "comprehensive health care services" to its members. The law defines the term "comprehensive health care services" to mean services, medical equipment and supplies, treatment of disease, or correction of defects for human beings.

It is generally left to a health insurer or managed care organization to indicate in its policy the specific services and treatment covered and excluded by the contract. However, OIR is authorized by law to prohibit the use of forms the office determines to be unfairly discriminatory or misleading. Competition among providers also helps determine the level of services and care each will provide to its policyholders.

¹⁶ Evans, J.; 2002; Lyme Disease; *Conn's Current Therapy*, pp. 127-132; R.E. Rakel, et al., editors; W.B. Saunders; Philadelphia.

¹⁷ Steer, A.C.; 2000; "Borrelia burgdorferi (Lyme disease, Lyme borreliosis)"; *Principles and Practice of Infectious Diseases*, 5th edition; vol. 2, pp. 2504-2518; G. Mandell et al., eds.; Churchill Livingstone.

¹⁸ See supra, Note 7.

¹⁹ See supra, Note 17.

Health Insurance Mandates/Required Benefits

Section 624.215, F.S., requires every person or organization seeking consideration of legislation to mandate a specific health coverage first to submit to the Agency for Health Care Administration (AHCA) and the Legislature a report assessing the social and financial impacts of the proposed benefit. The law requires the report to include the following information, if it is available:

- The extent to which the treatment or service is generally used by a significant portion of the population;
- The extent to which the insurance coverage is generally available;
- If the coverage is not generally available, to what extent does the lack of coverage result in unreasonable financial hardship;
- The level of public demand for the treatment or service;
- The level of public demand for insurance coverage of the treatment or service;
- The level of collective bargaining agents in negotiating for the inclusion of this benefit in group health contracts;
- The extent to which the coverage will increase or decrease the cost of the treatment or service;
- The extent to which the coverage will increase the appropriate uses of the treatment or service;
- The extent to which the coverage will be a substitute for a more expensive treatment or service;
- The extent to which the coverage will increase or decrease the administrative expenses of insurers and the premium and administrative expenses of policyholders; and
- The impact of providing this coverage on the total cost of health care.

To date, proponents of requiring insurance policies to cover treatment for Lyme disease have not prepared the report required by law.

Changes Proposed by the Bill

The bill creates the Panel on Lyme Disease to be headed by the Secretary of the Department of Health, or his or her designee. Three other agency heads also serve on the panel: the Commissioner of Insurance Regulation, the Secretary of Health Care Administration (AHCA), and the Insurance Consumer Advocate, or their respective designees.

The panel is directed by the bill to study issues relating to the diagnosis and treatment of Lyme disease and to consider the following information:

1. Appropriate medical treatments and interventions;
2. Costs associated with the treatment and interventions;
3. Implications of requiring individual and group health insurance policies, as well as health maintenance organizations, to cover appropriate treatments of Lyme disease; and
4. Other related information identified by panel members.

The panel is directed to seek input and information from persons diagnosed as having the disease, health care providers who treat Lyme disease, health insurers, public health officials, and other parties the panel determines have pertinent information about Lyme disease. The bill requires the panel to submit a report of its findings, including recommendations and suggested legislation, if appropriate, by February 15, 2007. The panel will deliver copies of the report to the Governor, the Senate President, the Speaker of the House of Representatives, the majority and minority leaders of both the Senate and the House, and to the substantive legislative committees having oversight of health insurance. The panel is authorized to include recommendations in its report for complying with s. 624.215, F.S., if appropriate. The bill repeals provisions creating the Panel on Lyme Disease June 30, 2007.

C. SECTION DIRECTORY:

Section 1 creates the Lyme Disease Panel; assigns members and duties to the panel; requires a report of the panel; and provides for the future repeal of the law governing the panel.

Section 2 specifies the bill takes effect upon becoming a law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

The bill requires the Department of Health, OIR, AHCA, and the Department of Financial Services to provide staff support to the panel in carrying out its duties. Although the affected agencies may incur some minor costs in support of the panel, such costs should be paid from existing appropriations to the respective agencies.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

None.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

On April 5, 2006, the Insurance Committee adopted a proposed committee substitute for HB 1013. The original bill required health insurance policies and health maintenance organization contracts to provide coverage for the diagnosis and treatment of Lyme disease, including long-term antibiotic therapy or other newly developed evidence-based therapy as deemed to be medically necessary by a physician. The bill as amended now only requires the creation of a panel on Lyme disease to study related issues as well as the submission of a report of the panel's findings and recommendations.

This staff analysis has been updated to reflect the bill as amended in the Insurance Committee.

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CHAMBER ACTION

The Insurance Committee recommends the following:

Council/Committee Substitute

Remove the entire bill and insert:

A bill to be entitled

An act relating to Lyme disease; creating the Panel on Lyme Disease; providing for membership, duties, and meetings; requiring a report and recommendations for legislation to the Governor and Legislature; providing for repeal of the panel; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Panel on Lyme Disease.--

(1) There is created the Panel on Lyme Disease. The Secretary of Health, or his or her designee, shall serve as head of the panel. The Commissioner of Insurance Regulation, the Insurance Consumer Advocate, and the Secretary of Health Care Administration, or their respective designees, shall serve as panelists. The departments and agencies represented on the panel shall provide staff support and resources to the panel. The panel shall meet as often as necessary to carry out its duties.

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23 (2) The panel shall study the issues relating to the
24 diagnosis and treatment of Lyme disease, including such factors
25 as appropriate medical treatments and interventions, the costs
26 associated with the treatment and interventions, the
27 implications of requiring group and individual health insurance
28 policies, as well as managed care organizations, to cover
29 appropriate treatments for Lyme disease, and other related
30 subjects identified by the panel.

31 (3) The panel shall seek input, comments, information, and
32 recommendations regarding Lyme disease from persons diagnosed as
33 having the disease, health care providers who treat Lyme
34 disease, health insurers, public health officials, and other
35 parties determined by the panel to have pertinent information
36 regarding Lyme disease.

37 (4) The panel shall prepare a report of its findings,
38 including recommended legislation, if appropriate, by February
39 15, 2007. The report shall be submitted to the Governor, the
40 Speaker of the House of Representatives, the President of the
41 Senate, the majority and minority leaders of each house of the
42 Legislature, and the chairs of the standing committees of each
43 house of the Legislature having jurisdiction over health
44 insurance issues. The panel may include in its report
45 recommendations for complying with s. 624.215, Florida Statutes,
46 as appropriate.

47 (5) This section is repealed June 30, 2007.

48 Section 2. This act shall take effect upon becoming a law.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1073 Reproductive Health Services
SPONSOR(S): Roberson and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 2458

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care General Committee		Halperin <i>PH</i>	Brown-Barrios <i>B3</i>
2) PreK-12 Committee			
3) Health Care Appropriations Committee			
4) Education Appropriations Committee			
5) Health & Families Council			

SUMMARY ANALYSIS

HB 1073 requires health information on family planning methods, referrals, and basic reproductive health services to be available on the Department of Health (DOH) website. This is intended to increase public access to family planning services, including early cancer screenings, contraception, and annual exams.

The bill requires all school districts to develop a plan to provide comprehensive and medically accurate family life and human sexuality education in schools. The bill intends for the curriculum to respect community values and encourage family communication; provide education that is medically accurate and age appropriate; and promote responsible behavior, including, but not limited to, the promotion of abstinence.

The bill requires that health care providers offer rape victims information on pregnancy prevention prophylaxis, and to provide such prophylaxis if requested and deemed medically appropriate.

If enacted, the bill takes effect on the date it becomes law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Promote Personal Responsibility – The bill requires school districts to emphasize individual responsibility within a comprehensive family life and human sexuality education curriculum.

Empower Families – The bill increases the amount and accessibility of information to Floridians on family planning and reproductive health services.

Provide Limited Government -- The bill creates additional requirements and regulations for schools and government agencies.

B. EFFECT OF PROPOSED CHANGES:

Family Planning information provided by the Department of Health website

HB 1073 requires health information on family planning methods, referrals to community resources to assist women and families in preventing unintended pregnancies, and basic reproductive health services to be available on the Department of Health (DOH) website. This is intended to increase public access to family planning services, including early cancer screenings, contraception, and annual exams. To accommodate the requirements of the bill, the department would increase the scope and accessibility of its current family planning website. The department would add information to the website or arrange current information in a way that consumers can access it more readily.

Require school districts to develop curriculum for family life and human sexuality education

The bill requires all school districts to develop a plan to provide comprehensive and medically accurate family life and human sexuality education in schools no later than the 2008-2009 school year. The bill stipulates that K-12 curriculum include:

- Respecting community values and encouraging family communication;
- Developing skills in communication, decision-making, and conflict resolution;
- Developing healthy relationships;
- Providing human development and sexuality education that is medically accurate and age appropriate;
- Promoting responsible behavior, including, but not limited to, the promotion of abstinence;
- Addressing the medically accurate use of contraception; and
- Promoting individual responsibility.

The bill gives individuals the opportunity to hold districts accountable for these provisions by establishing a process for reporting suspected incidents of noncompliance with teaching as prescribed by this section. The process includes reporting to the Auditor General, with findings forwarded to the Attorney General. If it is found that the district is not in compliance and does not satisfy the requirements, they shall be considered to have not met the objectives of the school improvement plan.

Access to Emergency Contraception for sexual assault patients

The bill requires health care providers and health care facilities¹ to offer information to rape victims on pregnancy prevention prophylaxis, and provide such prophylaxis if requested and deemed medically appropriate. Treatment provided to a rape survivor shall:

¹ Health care practitioners are defined as those as licensed under Chapters 458, 459, or 464, F.S.; and health care facilities are defined as those licensed under Chapter 395, F.S.

- Provide each rape survivor with medically and factually accurate and clear information about pregnancy prevention prophylaxis, including its indications and contraindications and risks associated with its use
- Inform each rape survivor of the survivor's medical option to receive pregnancy prevention prophylaxis; and
- Immediately prescribe or provide contraception to the rape survivor, if it is requested and if it is considered by the practitioner to be medically appropriate.

If enacted, the bill takes effect on the date it becomes law.

BACKGROUND

Family Planning Resources

A 2001 review conducted by the Florida State University Center for Prevention and Early Intervention Policy, in conjunction with the Department of Health (DOH) Family Planning Program, assessed the number of women in Florida in need of family planning services. Data from each county health department determined that the Statewide Family Planning Program and other providers are serving only 26 percent of women in need of family planning services.² According to other estimates by the Guttmacher Institute, approximately 1,726,160 women in Florida are in need of contraceptive services and supplies. Of these, 886,250 women need publicly supported contraceptive services because they have incomes below 250% of the federal poverty level or are sexually active teenagers. Florida has 311 publicly funded family planning clinics that serve approximately 30 percent of all women in need of publicly supported contraceptive services and 32% of teenagers in need.³

Teen Pregnancy

Florida currently is number six in the country for the number of teen pregnancies, with approximately 50,000 occurring each year, of which approximately 52 percent result in live births and 34 percent result in abortions. Florida's teenage pregnancy rate declined by 2 percent between 1992 and 2000. For Florida teens, AIDS and AIDS-related illnesses are the ninth leading cause of death.⁴ Florida also ranks third in the country in 2004 for the number of residents living with HIV/AIDS.⁵

Family Planning resources on the Department of Health website

Florida law currently requires DOH to provide family planning and maternal health information, assistance, and services to citizens of childbearing age. The department currently addresses the prevention of unwanted pregnancies through shared efforts between the department's family planning, comprehensive school health, and abstinence education programs. Family planning consists of an array of services such as preconception risk assessment, contraception, screening for sexually transmitted diseases, and pregnancy testing. The abstinence program is run through in-school programs, out-of-school programs, and public and private projects throughout the state.⁶ The goal of the program is to reduce unplanned pregnancies and promote positive pregnancy outcomes. The program is intended to improve maternal and infant health, reduce the incidence of abortion, and lower rates of sexually transmitted diseases, including HIV.

The department currently has a Family Planning website with information on contraceptive methods and referrals to community providers. In addition to including the information required by statute, the website also lists a comprehensive package of services that the department provides, FDA approved methods of contraceptives, and county health department family planning clinics.

² The Florida State University Institute of Science and Public Affairs, Center for Prevention and Early Intervention Policy, letter to Dr. Jean Malecki, Director, Palm Beach County Health Department. July 16, 2001.

³ Guttmacher Institute, http://www.guttmacher.org/pubs/state_data/states/florida.html.

⁴ Communication with Stephanie Grutman, Executive Director for the Florida Association of Planned Parenthood Alliances, Inc. March 28, 2006.

⁵ Kaiser Family Health Foundation <http://www.statehealthfacts.org/cgi-bin/healthfacts.cgi?action=compare&category=HIV%2fAIDS&subcategory=Persons+Living+with+AIDS&topic=Persons+Living+with+AIDS+All+Ages>

⁶ Information provided by the Department of Health bill analysis on HB 1073; March 28, 2006.

Education curriculum

Current law includes topic areas to be addressed in family life and human sexuality education curriculum, but does not prescribe specific information and skills. These are currently local decisions that school districts make. Section 1003.41, F.S., states that in order for high school students to graduate, they must receive one-half credit in "life management skills" in either ninth or tenth grade. The course is required to include instruction in the prevention of HIV/AIDS and sexually transmitted diseases (STDs), the benefits of sexual abstinence, and the consequences of teen pregnancy. School boards may decide to permit additional content regarding HIV/AIDS including information about how to control the spread of the disease.

Section 1003.41, F.S., provides that all instruction and course material must:

- Teach abstinence from sexual activity outside marriage as the expected standard for all school-age students while teaching the benefits of monogamous heterosexual marriage;
- Emphasize that abstinence from sexual activity is a way to avoid out-of-wedlock pregnancy, sexually transmitted diseases, including acquired immune deficiency syndrome, and other associated health problems;
- Teach that each student has the power to control personal behavior and encourage students to base actions on reasoning, self-esteem, and respect for others; and
- Provide instruction and material that is appropriate for the grade and age of the student.

Rape and sexual assault in Florida

Florida statistics on sexual violence are gathered by the Florida Department of Law Enforcement. In 2003, there were 12,756 reported sexual offenses in Florida, of which 6,724 were forcible rapes, 401 attempted rapes, and 1,596 forcible sodomies. The FBI estimates that only 37 percent of rapes are reported, and the Bureau of Justice estimates that only 30.7 percent of rapes are reported. It is estimated that approximately 11.1 percent, or 1 in 9 adult women in Florida have been victims of one or more forcible rapes in their lifetime. This prevalence is somewhat lower than the national estimate of approximately 13.4 percent.⁷ Approximately 1 percent to 5 percent of these assaults resulted in pregnancy.⁸

According to DOH, most county health departments currently refer rape victims to a rape crisis center or an emergency room to perform a forensics exam. Rape Crisis centers provide information and referral, crisis intervention, advocacy and support, therapy, and medical intervention. County health departments may be utilized to provide information to rape victims regarding pregnancy prevention and prophylaxis options.

Background on Emergency Contraceptives

Emergency Contraception (EC) provides a method for preventing pregnancy after sexual assault. It can reduce the risk of pregnancy up to 89 percent after unprotected intercourse and can be effective up to 120 hours following intercourse. Currently, Plan-B® is the one designated product approved by the Food and Drug Administration (FDA) specifically for use as an EC. Plan-B® is a high dose oral contraceptive pill that prevents pregnancy. Although EC is often confused with the "abortion pill" (RU-486/Mifepristone), EC does not cause an abortion and has no effect on an existing pregnancy. EC is recommended by the American College of Obstetricians and Gynecologists and the Florida Medical Association to be provided to sexual assault patients. Nationwide, the price of ECs ranges from \$20–\$25.

Currently, most emergency care facilities in Florida do not provide sexual assault victims with EC. Only 35 percent of such facilities provide EC on-site to victims. The majority of facilities, 47 percent, provide

⁷ Ruggiero, K.J., & Kilpatrick, D.G. (2003). Rape in Florida: A Report to the State. Charleston, SC: National Violence Against Women Prevention Research Center, Medical University of South Carolina. http://www.fcasv.org/2005_Web/Statistics/OneNineReport.pdf.

⁸ Florida Council Against Sexual Violence. March 28, 2006. www.fcasv.org.

EC on an inconsistent basis, where provision depends on an individual physician's discretion, the patient's age or whether the facility happens to have EC in stock. According to the Florida Council Against Sexual Violence, hospitals and rape treatment programs are only reimbursed \$250 per exam by the Attorney General's Victim Compensation program, which does not adequately cover the costs of the exam. If implemented, this bill would speak specifically to the establishment of formal policy on the provision of ECs for sexual assault patients, and would increase the uniformity of EC procedure.

C. SECTION DIRECTORY:

Section 1. Identifies the bill as the "Prevention First Act."

Section 2. Requires the Department of Health to develop and maintain information and resources on family planning and reproductive health services on the department website.

Section 3. Requires all school districts to develop a comprehensive family life and human sexuality education curriculum.

Section 4. Requires health care practitioners to provide rape survivors with medically accurate information about pregnancy prevention prophylaxis, and provide such contraception if the rape survivor requests it and the practitioner determines it is medically appropriate.

Section 5. Provides an effective date.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

According to analyses by the Department of Education⁹, the bill may incur costs for the Auditor General and Attorney General resulting from complaints against districts for not providing the educational requirements of the bill.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

According to analyses by the Department of Education¹⁰, there may be a fiscal impact on local governments. The bill requires school districts to develop comprehensive family life and human sexuality education by the 2008-09 school year. Districts would incur costs for research and development as well as for increased instructional requirements for students upon implementation of the requirements of the bill. The curriculum required by the bill would have to be developed for a minimum of four grade groupings, early elementary (K-2), elementary (3-5), middle (6-8), and high school (9-12). Districts would have to purchase or develop curriculum tools and manipulatives, as well as provide training to teachers and administrators.

⁹ Department of Health analysis on HB 1073 – Prevention First – March 30, 2006.

¹⁰ Department of Health analysis on HB 1073 – Prevention First – March 30, 2006.

Districts would have the option of purchasing commercially developed curriculums which can be costly. Currently, approximately 600 schools in Florida participate in a web-based educational program - Discovery Health Connection - which provides web-based instruction in 8 different curriculum areas including tobacco, obesity, and aids/sexuality education. The cost for current participants is \$500 per school; however, new schools choosing to participate in order to meet the requirements of the bill would incur an increased cost of \$1,695 per school. The program provides all curriculum tools as well as training for teachers and administrators.

As an alternative to purchasing a curriculum, districts could also establish curriculum by developing teams comprised of experts representative of community interests and knowledgeable in the field of human sexuality. Specific curriculum requirements, per the bill, may limit a school district's ability to address specific community interests and concerns.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

This bill requires health care practitioners to provide information on emergency contraceptives and to provide ECs when requested by a rape victim and when medically necessary. This may increase some costs for health care providers.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or taken an action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None

C. DRAFTING ISSUES OR OTHER COMMENTS:

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

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1 A bill to be entitled

2 An act relating to reproductive health services; creating
3 the Prevention First Act; requiring the Secretary of
4 Health to develop and maintain on the department's
5 Internet website information on family planning and
6 referrals to local community resources to assist women and
7 families in preventing unintended pregnancies; requiring
8 school districts to develop a comprehensive family life
9 and human sexuality education curriculum; providing
10 requirements for the curriculum; providing conditions
11 under which the curriculum may be audited; providing
12 definitions relating to the treatment of rape survivors;
13 providing duties of licensed health care facilities and
14 practitioners relating to the treatment of rape survivors;
15 providing an effective date.

16
17 WHEREAS, the Legislature finds that many women and teens in
18 the state do not have access to birth control and information
19 about family planning, and

20 WHEREAS, the Legislature finds that the victimization of
21 women through rape is compounded by the possibility that the
22 rape survivor may suffer an unwanted pregnancy by the rapist,
23 half of which end in abortion, and

24 WHEREAS, the Legislature further finds that providing
25 access to family planning information, contraception, and
26 pregnancy prevention prophylaxis will prevent abortions and
27 unintended pregnancies, thereby significantly reducing the

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number of women and teens who need medical assistance, Medicaid, KidCare, and other social services, and

WHEREAS, the Legislature recognizes that the most recent study of women in need of family planning services by the Florida State University Center for Prevention and Early Intervention Policy found that only 26 percent of women in Florida in need of family planning services are currently receiving the services, and

WHEREAS, the Legislature further recognizes that in the most recent peer-reviewed study of family planning cost-effectiveness, an analysis of California's family planning program showed that for every \$1 million spent on family planning, more than 900 unintended pregnancies were prevented and more than 350 abortions were avoided, and the unintended pregnancies prevented by the California family planning efforts saved an estimated \$4.48 in public expenditures for every \$1 spent, NOW, THEREFORE,

Be It Enacted by the Legislature of the State of Florida:

Section 1. This act may be cited as the "Prevention First Act."

Section 2. Family planning.--The Secretary of Health shall develop and maintain, on the Department of Health's Internet website, information on family planning and referrals to local community resources to assist women and families in preventing unintended pregnancies. The website must provide information on:

55 (1) Family planning methods, including all methods of
56 contraception and natural family planning approved by the
57 Federal Drug Administration.

58 (2) Basic preventive reproductive health services,
59 including breast and gynecological examinations, cervical cancer
60 screenings, screenings for sexually transmitted diseases,
61 including human immunodeficiency virus (HIV), and pregnancy
62 diagnosis and counseling.

63 (3) Referrals to local community providers and resources,
64 including subsidized family planning services, that provide
65 family planning services and counseling and basic preventive
66 reproductive health services.

67 Section 3. Comprehensive family life and human sexuality
68 education.--

69 (1) All school districts shall develop a comprehensive
70 family life and human sexuality education curriculum no later
71 than the 2008-2009 school year.

72 (2) For the purposes of this section, the term
73 "comprehensive family life and human sexuality education" means
74 education in kindergarten through grade 12 that:

75 (a) Respects community values and encourages family
76 communication.

77 (b) Develops skills in communication, decisionmaking, and
78 conflict resolution.

79 (c) Contributes to healthy relationships.

80 (d) Provides human development and sexuality education
81 that is medically accurate and age appropriate.

82 (e) Promotes responsible behavior, including, but not
83 limited to, the promotion of abstinence.

84 (f) Addresses the medically accurate use of contraception.

85 (g) Promotes individual responsibility.

86 (3) If any individual believes that the local school
87 district is not complying with this section, the individual may
88 request in writing to the Auditor General that the local school
89 district's family life and human sexuality curriculum be
90 audited. If the Auditor General finds that the local school
91 district has violated this section, the audit finding shall be
92 forwarded to the Attorney General. If the Attorney General
93 agrees with the Auditor General's findings, the Attorney General
94 shall advise the school district that both the Auditor General
95 and the Attorney General have determined that the school
96 district is not in compliance with the requirements of this
97 section. Any school district that does not correct the
98 deficiencies in its family life and human sexuality curriculum
99 to the satisfaction of both the Auditor General and the Attorney
100 General in a timely manner shall be considered to have not met
101 the objectives of any school improvement plan of the district.

102 Section 4. Treatment for survivors of rape.--

103 (1) As used in this section, the term:

104 (a) "Care to a rape survivor" means medical examinations,
105 procedures, and services provided to a rape survivor.

106 (b) "Incest" means a sexual offense described in s.
107 826.04, Florida Statutes.

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108 (c) "Pregnancy prevention prophylaxis" means any drug or
109 device approved by the federal Food and Drug Administration that
110 prevents pregnancy after sexual intercourse.

111 (d) "Rape" means sexual battery as described in ss.
112 794.011 and 827.071, Florida Statutes.

113 (e) "Rape survivor" means a person who alleges or is
114 alleged to have been raped or is the victim of alleged incest
115 and, because of the alleged offense, seeks treatment as a
116 patient.

117 (2) A health care practitioner licensed under chapter 458,
118 chapter 459, or chapter 464, Florida Statutes, or a health care
119 facility licensed under chapter 395, Florida Statutes, that
120 provides care to a rape survivor shall:

121 (a) Provide each rape survivor with medically and
122 factually accurate, clear, and concise information about
123 pregnancy prevention prophylaxis, including its indications and
124 contraindications and risks associated with its use.

125 (b) Inform each rape survivor of the survivor's medical
126 option to receive pregnancy prevention prophylaxis.

127 (c) If pregnancy prevention prophylaxis is requested,
128 immediately prescribe or provide the rape survivor with
129 pregnancy prevention prophylaxis if it is determined by the
130 practitioner to be medically appropriate.

131 Section 5. This act shall take effect upon becoming a law.

Overview of Strike-All Amendment for HB 1073

This strike-amendment to HB 1073 makes a few minor technical changes to make it identical to the Senate bill. The only substantive changes to the bill are in Section 3, regarding “comprehensive family life and sexuality education.”

In the original bill:

- It was the responsibility of each school district to develop a comprehensive family life and sexuality education curriculum, by the 2008-2009 school year.
- Individuals could request the Auditor General / Attorney General to conduct audits and penalize schools for noncompliance with these curriculum requirements.

In the amended bill:

- It is the responsibility of the Department of Education to develop a plan to provide comprehensive family life and sexuality education
- This is to be completed no later than the 2009-2010 school year.
- The “audit” provisions above are deleted.

The bill as amended does the following:

Section 1. Identifies the bill as the “Prevention First Act.”

Section 2. Requires DOH website to include info on family planning and reproductive health.

Currently, most of the following information is already on the site but may need rearranging to make it more user-friendly. These items include:

- Family planning methods;
- Referrals to community resources to assist women and families in preventing unintended pregnancies; and
- Basic reproductive health services.

Section 3. Requires DOE to develop comprehensive family life and sex ed curriculum (K-12).

Currently, districts decide content of curriculum. The bill stipulates that K-12 curriculum include:

- Respecting community values and encouraging family communication;
- Developing skills in communication, decision-making, and conflict resolution;
- Developing healthy relationships;
- Providing human development and sexuality education that is medically accurate and age appropriate;
- Promoting responsible behavior, including, but not limited to, the promotion of abstinence;
- Addressing the medically accurate use of contraception; and
- Promoting individual responsibility.

Section 4. Requires healthcare practitioners to provide rape victims with:

- Provide rape victims with medically accurate and concise info on pregnancy prevention prophylaxis, including its indications and contraindications;
- Inform each female rape survivor of her medical option to receive Emergency Contraception;
- Provide EC if the patient requests it and the practitioner determines it is medically appropriate.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. (for drafter's use only)

Bill No. **HB 1073**

COUNCIL/COMMITTEE ACTION

ADOPTED _____ (Y/N)
ADOPTED AS AMENDED _____ (Y/N)
ADOPTED W/O OBJECTION _____ (Y/N)
FAILED TO ADOPT _____ (Y/N)
WITHDRAWN _____ (Y/N)
OTHER _____

Council/Committee hearing bill: Health Care General Committee
Representative(s) Roberson offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. This act may be cited as the "Prevention First Act."

Section 2. The Secretary of Health shall develop and maintain, as part of the Department of Health's website, information on family planning and referrals to local community resources to assist women and families in preventing unintended pregnancies. The website must provide information on:

(1) Family planning methods, including all methods of contraception and natural family planning approved by the federal Food and Drug Administration.

(2) Basic reproductive health procedures, including breast and pelvic examinations; cervical cancer screenings; screenings for sexually transmitted diseases and the human immunodeficiency virus; and pregnancy diagnosis and counseling.

(3) Referrals to local community providers and resources, including subsidized family planning providers, that provide

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HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. (for drafter's use only)

family planning services and counseling and basic contraceptive, pregnancy-preventive, and reproductive health services.

Section 3. Comprehensive family life and sexuality education.--

(1) The Department of Education shall develop a plan to provide comprehensive family life and sexuality education no later than the 2009-2010 school year and shall implement such plan by the following school year.

(2) As used in this section, the term "comprehensive family life and sexuality education" means education in kindergarten through grade 12 which:

(a) Respects community values and encourages family communication.

(b) Develops skills in communication, decisionmaking, and conflict resolution.

(c) Contributes to healthy relationships.

(d) Provides education in human development and sexuality which is medically accurate and age appropriate.

(e) Promotes responsible behavior, including, but not limited to, the promotion of abstinence.

(f) Addresses the medically accurate use of contraception measures.

(g) Promotes individual responsibility.

Section 4. Treatment for survivors of rape.--

(1) DEFINITIONS.--As used in this section, the term:

(a) "Care to a rape survivor" means medical examinations, procedures, and services provided to a rape survivor.

(b) "Incest" means a sexual offense described in s. 826.04, Florida Statutes.

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HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. (for drafter's use only)

(c) "Pregnancy prevention prophylaxis" means any drug or device approved by the federal Food and Drug Administration which prevents pregnancy after sexual intercourse.

(d) "Rape" means sexual battery as described in ss. 794.011 and 827.071, Florida Statutes.

(e) "Rape survivor" means a person who alleges or is alleged to have been raped or is the victim of alleged incest and, because of the alleged offense, seeks treatment as a patient.

(2) DUTIES OF LICENSED PRACTITIONERS AND FACILITIES.--

(a) A health care practitioner licensed under chapter 458, chapter 459, or chapter 464, Florida Statutes, or a health care facility licensed under chapter 395, Florida Statutes, which provides care to a rape survivor shall:

1. Provide each rape survivor with medically and factually accurate, clear, and concise information concerning pregnancy prevention prophylaxis, including its indications and contraindications and risks associated with its use.

2. Inform each female rape survivor of her medical option to receive pregnancy prevention prophylaxis.

(b) If pregnancy prevention prophylaxis is requested, the health care practitioner shall immediately prescribe or provide the rape survivor with pregnancy prevention prophylaxis if it is determined by the practitioner to be medically appropriate.

Section 5. This act shall take effect upon becoming a law.

===== T I T L E A M E N D M E N T =====

Remove the entire title and insert:

A bill to be entitled

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HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. (for drafter's use only)

80 An act relating to reproductive health services and family
81 planning; creating the Prevention First Act; requiring the
82 Secretary of Health to develop and maintain certain
83 information on family planning and resources on the
84 website of the Department of Health; requiring that the
85 website contain certain information concerning family
86 planning and health services; requiring the Department of
87 Education to develop a comprehensive family life and
88 sexuality education plan; providing definitions; providing
89 duties of licensed health care facilities and
90 practitioners relating to treatment of rape survivors;
91 providing an effective date.

92
93 WHEREAS, the Legislature finds that many Florida women and
94 teens do not have access to birth control and information about
95 family planning, and

96 WHEREAS, the Legislature finds that the victimization of
97 women through rape is compounded by the possibility that the
98 rape survivors may suffer unwanted pregnancies, and half of such
99 pregnancies end in abortion, and

100 WHEREAS, the Legislature further finds that providing
101 access to family planning information, contraception, and
102 pregnancy prevention prophylaxis will prevent abortions and
103 unintended pregnancies, thereby significantly reducing the
104 number of women and teens who need medical assistance, Medicaid,
105 KidCare, and other social services, and

106 WHEREAS, the Legislature recognizes that the most recent
107 study of women in need of family planning services by the
108 Florida State University Center for Prevention and Early
109 Intervention Policy found that only 26 percent of women in this

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HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. (for drafter's use only)

110 state who are in need of such services are currently receiving
111 them, and

112 WHEREAS, the Legislature further recognizes that in the
113 most recent peer-reviewed study of the cost-effectiveness of
114 family planning services, an analysis of California's program
115 showed that for every \$1 million spent on family planning, more
116 than 900 unintended pregnancies were prevented and more than 350
117 abortions were avoided, and the unintended pregnancies prevented
118 by the family planning efforts in California saved an estimated
119 \$4.48 in public expenditures for every \$1 spent, NOW, THEREFORE,

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